

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 July 2000 (27.07.2000)

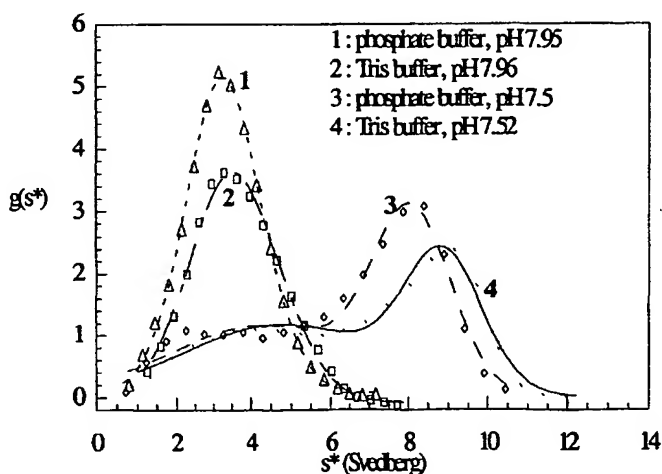
PCT

(10) International Publication Number
WO 00/43034 A3

- (51) International Patent Classification⁷: **A61K 38/28**, 47/10, 47/02, 47/26 (74) Agents: BENT, Stephen, A. et al.; Foley & Lardner, Suite 500, 3000 K Street, N.W., Washington, DC 20007-5109 (US).
- (21) International Application Number: PCT/US00/01627
- (22) International Filing Date: 26 January 2000 (26.01.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/117,291 26 January 1999 (26.01.1999) US
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- (81) Designated States (national): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:
— With international search report.

[Continued on next page]

(54) Title: MONODISPERSE HEXAMERIC ACYLATED INSULIN ANALOG FORMULATIONS



(57) Abstract: The present invention provides formulations and methods for preparing formulations containing an aqueous solution at a pH of greater than about 7.9. The aqueous solution includes an isotonicity agent, a phenolic derivative, zinc ions, and an acylated human insulin analog. More particularly, the invention relates to formulations having a pH of greater than about 7.9 that include a monoacylated human insulin analog such as an acylated des(B30) human insulin analog or an analog that comprises a native or modified human insulin A chain optionally modified at position A21, and a modified native human insulin B chain optionally modified at position B3 and modified at position B28, or at both positions B28 and B29, and that contains a lysine residue at either position B28 or B29 acylated with a fatty acid residue. The invention also provides a method for treating a patient suffering from hyperglycemia using the pharmaceutical formulations of the invention.



— Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(88) Date of publication of the international search report:
28 December 2000

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 00/01627

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K38/28 A61K47/10 A61K47/02 A61K47/26

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 48414 A (NOVO NORDISK) 24 December 1997 (1997-12-24) claims 1-18 page 5, line 5 - line 13 page 6, line 1 - line 3 ---	1-59
P, X	WO 99 34821 A (NOVO NORDISK) 15 July 1999 (1999-07-15) claims 1-14 page 9; example 1 ---	1-59
A	WO 98 34953 A (NOVO NORDISK) 13 August 1998 (1998-08-13) the whole document -----	1-59

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search

7 November 2000

Date of mailing of the international search report

14/11/2000

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Ventura Amat, A

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/01627

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